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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,891	08/09/2000	Francesco Cerrina	030206:0527	6809

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/637,891

Applicant(s)

CERRINA ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>(2 sheets)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Review of the instant application has revealed significant issues that support withdrawal of the previously set forth Notice of Suspension, mailed 11/3/04. Therefore, the suspension in said Notice is hereby withdrawn.

Applicants' arguments, filed 8/18/03, have been fully considered and they have been indicated previously as being persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, however, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

ABSTRACT

The abstract of the disclosure is objected to because exceeds 150 words. Applicants are hereby required to submit an abstract on its own separate sheet of paper which is 150 words or less in length. Correction is required. See MPEP § 608.01(b).

VAGUENESS AND INDEFINITENESS

Claims 1-36, 38, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the first 2 lines of claim 1, the apparatus is cited as being directed to the synthesis of arrays of DNA probes. Confusingly, there is(are) no DNA probe synthesis limitation(s) per se cited anywhere in components (a) or (b) of claim 1. It is acknowledged that an active surface is cited in step (a) but without any requirement that the surface is synthesized with a DNA probe array. In fact, the surface is cited as being

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of the type whereon such an array "may be formed", thus apparently being inclusive of a surface on which other materials may be added other than such an array. Also, commonly a probe in such an array is constructed which has the characteristics of being complementary to a target nucleic acid sequence so that hybridization may be attempted in order to detect the presence or absence of the target in a sample. No such complementarity is required in instant claim 1. Thus, the claim is vague and indefinite as to whether the preamble, lines 1-2, controls the metes and bounds of the claim or the generic components listed in (a) - (b) which apparently may synthesize any product thereon even without any probe considerations. Independent claim 21 also contains this unclarity. Clarification via clearer claim wording is requested. Claims dependent directly or indirectly from claims 1 or 21 are also rejected hereinunder due to their dependence being inclusive of the above vagueness and indefiniteness.

Claim 24 is vague and indefinite due to citing a magnification of one, albeit substantially. It is confusing what is meant by citing a magnification of one when a 1X image is commonly known to be the same size as the item being imaged and thus is not a magnification. Clarification via clearer claim wording is requested.

LACK OF ENABLEMENT

Claims 14 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

In claim 33 the reflective lens are required to form an Kohler illumination system. A Kohler illumination system limitation is also set forth in claim 14. The only guidance in the instant disclosure as filed for such a system is on page 11, lines 2-5, wherein a two element fused silica condenser is used with two plano-convex lenses and then named a Kohler illumination system without further explanation. Figure 3 depicts items 28 and 52 as the above components of the Kohler illumination system but without any indication of what enables the Kohler feature therein. Condenser and plano-convex lens are well known, but not the Kohler system arrangement. Thus, specific guidance as to what is meant by such a system is not set forth. Applicants also have not referenced any document as to Kohler illumination system detailed description. Thus, it would

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require undue experimentation to make such a system without further guidance as no predictable system criteria have been instantly set forth nor is well known in the art.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-10, 15, 21-23, 25-29, and 34 are rejected under 35

U.S.C. 102(e)(2) as being clearly anticipated by Gao et al. (P/N 6,426,184; already of record).

Gao et al. discloses the photo-generation of sequence arrays on solid surfaces in the title and abstract. In Figures 1-19 various aspects of such a practice with apparatus therefore are depicted. In particular Figure 8A shows a micromirror projection system with item 801a being micromirrors as required in instant claim 1, item (b)(2). Projection optic elements are also shown in Figure 8A, such as item 806, as also required in instant claim 1, part (b)(3). The substrates upon which DNA probe arrays may be formed as being active for this are depicted in Figures 1 - 7 regarding both the substrate with an active surface as well as array forming chemistry which is light activated. Figure 8A shows a light source providing a light beam as required in instant claim 1, item (b)(1). These elements are detailed in columns 7-30 of the reference. Computer

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control (instant claim 8) of the micromirrors is disclosed in column 30, lines 10-27, with electronic control further described in column 25, lines 34-45, via rocking mirror control (also at least 2 dimensions as in instant claim 2), as required in instant claim 1, (b)(2). It is noted that the reference qualifies as prior art via the disclosure of the above summarized invention in provisional application serial number 60/074,368; filed 2/11/98. An oblique angle is shown between items 805 and 801 for the light beam as required also in instant claim 3. Light filtering as in instant claim 5 is cited in the reference in column 25, lines 22-33, inclusive of an accepted range of ultraviolet wavelengths as cited in instant claims 9 and 10, thus also blocking others as in instant claim 10. In column 27, line 44, through column 28, line 25, light patterning via projection through transparent substrates is described and noted as depicted in Figures 9A - 9C which also shows such transmission through the substrate as is also shown in Figure 8A. These descriptions anticipate instant claim 6 and 7 when combined with the reagent flow discussions therein. Telecentric optical elements are shown in Figures 8A as well as reflective elements (805 and 801a) as required in instant claim 15.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 10, 2005


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER